

### **Remarks**

Claims 10-15 are currently pending in the instant application. Claim 15 stands objected to and Claims 10-15 stand rejected. Reconsideration of the claims in light of the amendments and remarks provided herein is respectfully requested.

#### Objection Due to Informality

Claim 15 stands objected to due to an informality. As Claim 15 has been corrected, see above, withdrawal of the objection is respectfully requested.

#### Rejection Under 35 U.S.C. §112, first paragraph

Claims 10-15 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are directed to a method for inhibiting or reducing tumor cell proliferation *in vivo* using a Rad51 inhibitor and a polynucleotide encoding p53. The claimed method is based on the fact that inhibiting Rad51 activity in tumor cells reduces tumor cell proliferation (See, page 6 lines 15-23 and references cited therein) and that this reduction can be combined with the increase in apoptosis known to occur with an increase in p53 concentration (See page 6, lines 24-28) to achieve a greater effect than either approach individually.

As Rad51 is known to have an ATPase activity, numerous examples of Rad51 inhibitors are provided in the form of non-hydrolyzable nucleotide analogues. (See, page 9, lines 4-26). In addition, as Rad51 is known to bind to DNA, examples of minor groove binding drugs are provided as alternative Rad51 inhibitors. (See, page 9, lines 27-30). Other small molecule Rad51 inhibitors could be isolated by employing routine activity screens in the presence of the potential inhibitor.

Polynucleotides coding for the p53 protein were well known at the time the application was filed, and several references cited in the application discuss methods of p53 gene therapy. (See, page 14, lines 11-22 and references cited therein).

The standard for enablement is whether one of skill in the art could make and use the claimed invention from the disclosures in the specification coupled with the information known

in the art without undue experimentation. (See, United States v. Teletronics, 8 USPQ2d 1217 (Fed Cir 1988)).

As the specification discloses various Rad51 inhibitors as well as methods of p53 gene therapy, it is clear that one of skill in the art would not have to resort to undue experimentation to perform the method as claimed. Accordingly, withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is requested.

Rejection Under 35 U.S.C. § 112, second paragraph

Claims 10-15 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. In particular, the Examiner asserts that Claims 10-15 depend from a canceled claim. As Claim 10 has been amended to incorporate the limitations of the canceled claim, Applicants respectfully request withdrawal of this rejection.

Claims 10-15 also stand rejected under 35 U.S.C. § 112, second paragraph, for not containing a step that positively refers back to the preamble of the claim. Withdrawal of this rejection, in light of the amendment to Claim 10 presented above, is respectfully requested.

### Conclusion

Applicants respectfully submit that the claims are in condition for allowance and early notification to that effect is respectfully requested. Please direct any calls in connection with this application to the undersigned attorney at (415) 781-1989.

Respectfully submitted,

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